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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,492	01/05/2001	Stephen G. Oliver	39-225	6022

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EXAMINER
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LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

21

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/700,492

Applicant(s)

OLIVER ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35, 37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 15-34 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 9-14 and 37 is/are allowed.
- 6) ☒ Claim(s) 6-8, 35 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Receipt is acknowledged of a reply, filed July 9, 2003 as Paper No. 21, to the previous Final Office Action. The amendments to the claims and specification have been entered.

Claims 1-35, 37 and 38 are pending in the instant application. After further consideration, claims 13 and 14 (corresponding to Group II as indicated in the previous restriction requirement) have been rejoined with the elected invention of Group I (claims 1-12, 35, 37 and 38). Claims 15-34 are withdrawn as being drawn to a non-elected invention. Claims 1-14, 35, 37 and 38 are therefore ready for examination in the instant application. Any rejection of record in the previous Office Action, Paper No. 18, mailed March 3, 2003, that is not addressed in this action has been withdrawn.

Regarding the previous Office Action, Applicant has indicated that page 2 of the Action appears to be directed to unrelated subject matter, and has requested that a substitute page 2 be submitted so as to correct the record. Applicant is hereby informed that the record as contained within the case file does indeed contain the correct page 2. Furthermore, the examiner has attached a copy of the proper page 2 to this Office Action, and apologizes for the miscommunication. If the proper page 2 does not arrive with the Office Action, applicant is encouraged to contact the examiner by telephone to correct this matter expeditiously. There were no rejections contained on the proper page 2 that were not addressed by Applicant in their response.

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The indicated allowability of claims 6-8, 35 and 38 is withdrawn for the reasons set forth below under 35 USC 112 first and second paragraph. Because this rejection is made under new grounds that are not necessitated by amendment, finality of the previous Office Action is WITHDRAWN, and prosecution is re-opened.

### *Claim Objections*

Claim 14 is objected to because of the following informalities: the term expressed appears to be misspelled "ex pressed". Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This is a new rejection that is not necessitated by amendment.**

It is apparent that the strains ZO123, ZO124 and ZO-126 are required to practice the invention as claimed. As such, the strains must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the strains. In the instant case, the process to generate the strains that is disclosed in

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the specification does not appear to be repeatable because there is no clear indication of the complete genetic background of the strains (Table 1 only displays the genetic background as it relates to specific selectable markers in the strains), therefore the skilled artisan could not envision when they were in possession of the specific strains that are indicated. Similarly, the strains do not appear to be readily available to the public.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

- a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;
- c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request for the enforceable life of the patent, whichever is longer;
- d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and
- e) the deposit will be replaced if it should ever become inviable.

Failure to make one of the preceding indications in response to this Office Action will result in the rejection being maintained in either a second Non-Final or a Final rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-8 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection that is not necessitated by amendment.**

Claims 6-8 and 35 recite the limitation “derived from” in reference to various recombinant vector constructs. The meaning of “derived from” is unclear because there is no clear definition of what comprises the derivation steps, or in what manner the vector is derived. In the specification, there are examples where these vectors are digested so as to produce a fragment to be used for integration into the chromosome of the host cell. However, it is unclear if this is what is meant by derivation, and limitations cannot be read into the claims from the specification. As such, the metes and bounds of the claim are indefinite.

***Allowable Subject Matter***

Claims 1-5, 9-14 and 38 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson  
July 25, 2003

DAVID GUZO  
PRIMARY EXAMINER  
